

COMMITTEE ON LEGISLATIVE RESEARCH
OVERSIGHT DIVISION

FISCAL NOTE

L.R. No.: 2680-01
Bill No.: HB 1315
Subject: Children and Minors; Health Care; Medical Procedures and Personnel;
Department of Health
Type: Original
Date: April 14, 2015

Bill Summary: This proposal expands the newborn screening requirements to include severe combined immunodeficiency (SCID).

FISCAL SUMMARY

ESTIMATED NET EFFECT ON GENERAL REVENUE FUND			
FUND AFFECTED	FY 2016	FY 2017	FY 2018
Total Estimated Net Effect on General Revenue			

ESTIMATED NET EFFECT ON OTHER STATE FUNDS			
FUND AFFECTED	FY 2016	FY 2017	FY 2018
MoPHS	(Less than \$14,139)	Could exceed \$34,927	Could exceed \$19,811
Total Estimated Net Effect on <u>Other</u> State Funds	(Less than \$14,139)	Could exceed \$34,927	Could exceed \$19,811

Numbers within parentheses: () indicate costs or losses.
This fiscal note contains 9 pages.

ESTIMATED NET EFFECT ON FEDERAL FUNDS			
FUND AFFECTED	FY 2016	FY 2017	FY 2018
Federal*	\$0	\$0	\$0
Total Estimated Net Effect on <u>All</u> Federal Funds	\$0	\$0	\$0

* Income and transfer-out nets to \$0.

ESTIMATED NET EFFECT ON FULL TIME EQUIVALENT (FTE)			
FUND AFFECTED	FY 2016	FY 2017	FY 2018
MoPHS	2	2	2
Total Estimated Net Effect on FTE	2	2	2

☐ Estimated Net Effect (expenditures or reduced revenues) expected to exceed \$100,000 in any of the three fiscal years after implementation of the act.

ESTIMATED NET EFFECT ON LOCAL FUNDS			
FUND AFFECTED	FY 2016	FY 2017	FY 2018
Local Government	\$0	\$0	\$0

FISCAL ANALYSIS

ASSUMPTION

Officials from the **Department of Health and Senior Services (DHSS)** provide the following assumptions:

Division of Community and Public Health

Adding severe combined immunodeficiency (SCID) to the newborn screening panel would result in approximately 20 or more cases per year that would require referral for follow-up and confirmation. However, due to the fact that the testing methodology for SCID is relatively new and based upon recent experience with Lysosomal Storage Disorders, it is recognized that 20 cases per year is the minimum estimated number and the actual referral rate could be significantly higher. Based on this knowledge, it is assumed that the tracking and follow-up of SCID would exceed the current capacity of the newborn screening program.

Due to the nature of SCID, it would not be appropriate to add funding to the existing genetic contracts because newborns referred for follow-up after an abnormal SCID newborn screen would not be seen or followed in the genetic clinics. These newborns would be seen by immunologists and, if necessary, transplant teams. Therefore, the newborn screening program would require one (1) Public Health Senior Nurse (\$49,788 annually) to conduct and coordinate all follow-up activities for SCID newborn screening.

The Public Health Senior Nurse responsibilities would include:

- Coordinating and facilitating a SCID Newborn Screening Task Force to advise the program in the implementation of SCID screening;
- Developing any necessary parent educational materials;
- Revising the newborn screening pamphlet;
- Collaborating with the Missouri State Public Health Laboratory to develop procedures for calling out high risk SCID newborn screening results;
- Collaborating with physicians, nurses, and other medical professionals to ensure all newborns with high risk SCID newborn screen are followed-up appropriately including all necessary evaluations and tests to confirm or rule out a disorder;
- Ensuring all confirmatory results and diagnoses are entered into the Missouri Health Strategic Architecture and Information Cooperative (MOHSAIC);
- Continually evaluate and monitor SCID newborn screening to ensure policies and procedures are in alignment with best practice and evidence-based standards of care; and
- Any additional tasks or duties related to SCID newborn screening.

The newborn screening pamphlet would need to be revised to include information on SCID. This would be a one-time cost of \$6,000 to revise and reprint the pamphlet (100,000 pamphlets X \$.06 each = \$6,000).

ASSUMPTION (continued)

State Public Health Laboratory (SPHL):

The State Public Health Laboratory (SPHL) would need to hire one (1) additional FTE's Senior Public Health Laboratory Scientist (\$41,940 annually) to oversee and maintain newborn screening for SCID.

The job description for Senior Public Health Laboratory Scientist includes:

- Opening daily samples received and assessing for quality and suitability;
- Processing samples into split samples for the SCID testing platforms;
- Comprising work lists, making necessary solutions, and performing instrument preparations;
- Performing the molecular amplification and detection procedures for the presence of T-Cell Receptor Excision Circles (TRECs) to detect SCID;
- Reviewing and interpreting test results, and conducting necessary re-testing of abnormal results;
- Assessing the risk of abnormal results and contacting appropriate genetic referral center for confirmation and follow-up testing.
- Reviewing and approval of daily instrument controls for accuracy;
- Monitoring QC results for shifts and trends, and performing corrective and preventive actions;
- Oversight of instrument performance, maintenance, and troubleshooting;
- Conducting and oversight of regular proficiency testing to assure accuracy and proficiency certifications;
- Training and cross-training new scientists to be proficient in the SCID section;
- Ordering testing reagents and maintaining good inventory of items necessary for continuation of operations; and,
- Compiling monthly, annual, and as-needed reports for the newborn screening manager.

All laboratory equipment and expense costs associated with SCID testing are based upon vendor quotes for technology currently available. The DHSS assumes the proposal will have a cost to the MoPHS Fund of \$656,962 for FY 2016; \$758,720 for FY 2017 and \$775,127 for FY 2018.

This proposed legislation would require the DHSS to increase the newborn screening fee which will be deposited in the Missouri Public Health Services (MoPHS) Fund. DHSS estimates that the fee will increase by \$9.00 when testing is begun with inflationary increases thereafter, as needed. Based on previous years, it is estimated the DHSS will perform 95,640 screens annually - 80,640 will be billed to the submitters and approximately 15,000 will be submitted to Medicaid.

ASSUMPTION (continued)

15,000 X \$7 (can only claim Medicaid for the lab portion) X 60% (Federal Medical Assistance Percentage rate) = \$63,000; 80,640 X \$9 = \$725,760; total annual income \$788,760 (\$63,000 + \$725,760).

The net estimated fiscal impact to the MoPHS Fund is expected to be \$338 for FY 2016; \$30,040 for FY 2017; and \$13,634 for FY 2018.

Oversight assumes the provisions of this proposal will take effect on January 1, 2016 when the state employee health insurance plan year goes into effect. In addition, Oversight assumes, based on the Department of Social Services, MO HealthNet response a 1.9% growth rate in Medicaid reimbursements for newborn screening expenses.

Officials from the **Department of Social Services (DSS), MO HealthNet Division (MHD)** state by January 1, 2016, the Department of Health and Senior Services (DHSS) shall, subject to appropriations, expand the newborn screening requirements in section 191.331 to include severe combined immunodeficiency (SCID), also know as bubble boy disease.

Currently, newborn screenings are reimbursed by the MHD for the federal portion only. The general revenue portion is included in the DHSS budget.

In FY 2014, the MHD was billed for approximately 15,000 newborn screenings by the State Health Lab. For this calculation, it is assumed the same number of screenings would be billed in FY 2016 as billed in FY 2014.

At this time, the rate for the additional newborn screenings is unknown. Using DHSS' estimates that the rate will be \$7.00, the result would be \$105,000 (\$7 X 15,000 newborn screenings).

Fiscal Impact: Unknown, but at least:

FY 2016 (calculated for 6 months): Total Federal Funds \$33,311;
FY 2017 (1.9% trend factor): Total Federal Funds \$67,888; and,
FY 2018 (1.9% trend factor): Total Federal Funds \$69,178.

Officials from the **Missouri Department of Transportation (MoDOT)** state the MoDOT's health plan could have increased costs by adding the screening to its newborn screening charges. The associated charges are unknown, but the anticipated impact is expected to be less than \$100,000 annually.

Oversight assumes MoDOT's costs for this additional newborn screening test will be minimal and, therefore, assumes the MoDOT can absorb this potential increase.

ASSUMPTION (continued)

Oversight assumes the changes to MoDOT's health insurance plan would be effective January 1, 2016, when the new employee health insurance plan year begins.

Officials from the **Joint Committee on Administrative Rules**, the **Missouri Consolidated Health Care Plan** and the **Missouri Department of Conservation** each assume the proposal would not fiscally impact their respective agencies.

Officials from the **Department of Public Safety, Missouri State Highway Patrol** defer to the Missouri Department of Transportation (MoDOT), Employee Benefits Section for response on behalf of the Highway Patrol. Please see MoDOT's fiscal note response for the potential fiscal impact of this proposal.

Officials from the **Office of the Secretary of State (SOS)** state many bills considered by the General Assembly include provisions allowing or requiring agencies to submit rules and regulations to implement the act. The SOS is provided with core funding to handle a certain amount of normal activity resulting from each year's legislative session. The fiscal impact for this fiscal note to the SOS for Administrative Rules is less than \$2,500. The SOS recognizes that this is a small amount and does not expect that additional funding would be required to meet these costs. However, the SOS also recognizes that many such bills may be passed by the General Assembly in a given year and that collectively the costs may be in excess of what the office can sustain with the core budget. Therefore, the SOS reserves the right to request funding for the cost of supporting administrative rules requirements should the need arise based on a review of the finally approved bills signed by the governor.

Oversight assumes the SOS could absorb the costs of printing and distributing regulations related to this proposal. If multiple bills pass which require the printing and distribution of regulations at substantial costs, the SOS could request funding through the appropriation process.

Officials from the following **hospitals**: Barton County Memorial Hospital, Bates County Memorial Hospital, Cedar County Memorial Hospital, Cooper County Hospital, Excelsior Springs Medical Center, Putnam County Memorial Hospital and Washington County Memorial Hospital did not respond to **Oversight's** request for a statement of fiscal impact.

Officials from the **University of Missouri** did not respond to **Oversight's** request for a statement of fiscal impact.

<u>FISCAL IMPACT - State Government</u>	FY 2016 (6 Mo.)	FY 2017	FY 2018
MoPHS FUND (§191.332)			
<u>Income - DHSS</u>			
Increase in infant screening revenues	\$362,880	\$725,760	\$725,760
<u>Transfer-in from DSS Federal Fund</u>			
Reimbursement for screening costs	<u>At least \$33,311</u>	<u>At least \$67,888</u>	<u>At least \$69,178</u>
Total <u>Income and Transfers-in - DHSS</u>	<u>At least</u> <u>\$396,191</u>	<u>At least</u> <u>\$793,648</u>	<u>At least</u> <u>\$794,938</u>
<u>Costs - DHSS</u>			
Personal service	(\$45,864)	(\$92,645)	(\$93,572)
Fringe benefits	(\$23,852)	(\$48,180)	(\$48,662)
Equipment and expense	<u>(\$340,614)</u>	<u>(\$617,896)</u>	<u>(\$632,893)</u>
Total <u>Costs - DHSS</u>	<u>(\$410,330)</u>	<u>(\$758,721)</u>	<u>(\$775,127)</u>
FTE Change	2 FTE	2 FTE	2 FTE
ESTIMATED NET EFFECT ON THE MoPHS FUND	<u>(Less than</u> <u>\$14,139)</u>	<u>Could exceed</u> <u>\$34,927</u>	<u>Could exceed</u> <u>\$19,811</u>
Estimated Net FTE Change for the MoPHS Fund	2 FTE	2 FTE	2 FTE
FEDERAL FUNDS (§191.332)			
<u>Income - DSS-MHD</u>			
Reimbursement for SCID newborn screening expenses	At least \$33,311	At least \$67,888	At least \$69,178
<u>Transfer-out - DSS-MHD</u>			
Transfer-out to DHSS MoPHS Fund for SCID newborn screening expenses	<u>(At least</u> <u>\$33,311)</u>	<u>(At least</u> <u>\$67,888)</u>	<u>(At least</u> <u>\$69,178)</u>
ESTIMATED NET EFFECT ON FEDERAL FUNDS	<u>\$0</u>	<u>\$0</u>	<u>\$0</u>

FISCAL IMPACT - Local Government

FY 2016
(10 Mo.)

FY 2017

FY 2018

\$0

\$0

\$0

FISCAL IMPACT - Small Business

Small business birthing centers, midwives and any other entities that purchase newborn screening collection forms would have to pay an additional fee. However, this cost may be recovered by the fees charged. There would also be additional administrative costs.

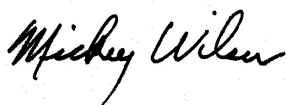
FISCAL DESCRIPTION

This proposal requires the Department of Health and Senior Services, subject to appropriations, to add severe combined immunodeficiency (SCID), also known as the bubble boy disease to the list of newborn screening requirements.

This legislation is not federally mandated and would not duplicate any other program, but may require additional capital improvements or rental space.

SOURCES OF INFORMATION

Department of Health and Senior Services
Department of Public Safety -
 Missouri State Highway Patrol
Department of Social Services
Joint Committee on Administrative Rules
Missouri Consolidated Health Care Plan
Missouri Department of Conservation
Missouri Department of Transportation
Office of Secretary of State



L.R. No. 2680-01
Bill No. HB 1315
Page 9 of 9
April 14, 2015

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